


# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 29625P WO	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/EP2004/004345	International filing date (day/month/year) 23.04.2004	Priority date (day/month/year) 23.04.2003	
International Patent Classification (IPC) or national classification and IPC C07K14/35, C07K14/195			
Applicant MAX-PLANCK-GESELLSCHAFT ZUR FÖRDERUNG DER... et al			
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 5 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of    sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).			
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I    Basis of the opinion <input type="checkbox"/> Box No. II    Priority <input type="checkbox"/> Box No. III    Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV    Lack of unity of invention <input checked="" type="checkbox"/> Box No. V    Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI    Certain documents cited <input type="checkbox"/> Box No. VII    Certain defects in the international application <input type="checkbox"/> Box No. VIII    Certain observations on the international application			
Date of submission of the demand  12.11.2004		Date of completion of this report  21.07.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Kalsner, I  Telephone No. +49 89 2399-8708	



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

10/554408  
JCO9 Rec'd PCT/PTO 24 OCT 2005  
International application No.  
PCT/EP2004/004345

---

**Box No. I Basis of the report**

---

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-20 as originally filed

**Sequence listings part of the description, Pages**

1-5 as originally filed

**Claims, Numbers**

1-38 as originally filed

**Drawings, Sheets**

1/4-4/4 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/004345

---

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

---

1. Statement

Novelty (N)	Yes: Claims	1-38
	No: Claims	
Inventive step (IS)	Yes: Claims	1-38
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-38
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**Ad Section V: Reasoned statement with regard to novelty, inventive step or industrial applicability**

**1) Documents**

D1...WO 99 10496

D2...Reyrat et al. (1995) PNAS 92: 8768-8772

D3...Reyrat et al. (1996) Infection and Immunity 64: 3934-3936

**2) Novelty and inventive step**

The present application relates to a urease deficient cell which comprises a recombinant nucleic acid molecule encoding a fusion polypeptide comprising a domain from a polypeptide capable of eliciting an immune response in a mammal and a phagolysosomal escape domain and its application as vaccine.

The claims are considered to meet the requirements of Art. 33(2) PCT as the prior art does not disclose a cell as defined in the claims.

**Claims 1-38** are also considered to meet the requirements of Art. 33(3) PCT for the following reasons:

D1 is considered to represent the closest prior art. D1 discloses a tuberculosis vaccine comprising as an active agent a cell comprising recombinant nucleic acid molecule encoding a fusion polypeptide comprising a domain from a polypeptide capable of eliciting an immune response in a mammal and a phagolysosomal escape domain.

The difference between the bacterial cell/vaccine disclosed in D1 and that of the present application lies in the fact that the cell of the present application is additionally required to be urease deficient.

The problem to be solved by the present application, thus can be seen in the provision of a bacterial cell useful for vaccination purposes which exhibits an

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

**PCT/EP2004/004345**

increased safety profile and an improved vaccine efficacy.

While urease has been discussed to contribute to bacterial virulence (D2, p. 5651, p. 5651, right col., 2<sup>nd</sup> full par.; D3, p. 3934, left col., 1<sup>st</sup> par.) it could not be derived from the prior art that a urease deficient strain would exhibit an improved vaccine efficacy.

